

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

**IN RE: DIGITEK PRODUCT LIABILITY  
LITIGATION**

**MDL NO. 1968**

---

**THIS DOCUMENT RELATES TO ALL CASES**

**REPLY IN SUPPORT OF MOTION *IN LIMINE* TO EXCLUDE UNRELIABLE  
HEARSAY**

Plaintiffs' Opposition to Defendant's Motion *In Limine* to Exclude Unreliable Hearsay asserts that it was appropriate for Dr. Bliesner (and all of Plaintiffs' general liability experts) to rely on an April 30, 2008 e-mail of a Massachusetts nursing home employee to form his expert opinion that there were defective Digitek® tablets in the market in 2008. (Doc. 551). Plaintiffs also state that the e-mail is not hearsay. (*Id.*) Plaintiffs ignore the appropriate standard and simply gloss over the substantial deficiencies of the e-mail.

**I. THE APRIL 30, 2008 IS CLEARLY HEARSAY**

Plaintiffs' Opposition states that the April 30, 2011 e-mail is not hearsay. (Doc. 551 at p. 1). But Plaintiffs do not actually make any argument to support this proposition. In fact, Plaintiffs essentially concede the document is hearsay by focusing on the ability of expert witnesses to properly rely on hearsay in forming their expert opinions. (Doc. 551 at 1-4).

There cannot be any real dispute that the April 30, 2011 e-mail is hearsay. The author, who is not a party to this litigation and has not been deposed, asserts in the e-mail that another employee observed a double-thick tablet in a blister pack. (Doc. 527-1 at 3). Plaintiffs intend to offer the document into evidence for the truth of the proposition that there were double-thick tablets produced by Actavis and released to market. The circumstances of Plaintiffs' intended

use of this document meet the classic definition of hearsay and Lynne Farrell's affidavit, even if it was allowed, does not cure this fact. Nor can there be any real dispute that none of the exceptions set forth in Fed. R. Evid. 803 apply. The document should be excluded from evidence.

**II. THE APRIL 30, 2008 E-MAIL CANNOT BE RELIED UPON BY AN EXPERT WITNESS TO CONCLUDE DEFECTIVE DIGITEK® WAS RELEASED.**

Plaintiffs claim the e-mail is reliable enough for their expert witnesses to rely upon when forming their opinions that defective Digitek® was released to market. (Doc. 551 at 1-4). Plaintiffs ignore the appropriate standard.

*Korsak v. Atlas Hotels, Inc.*, 2 Cal. App. 4th 1516 (1992), is a California state court case and is not binding on this Court. Even if this Court considers *Korsak* persuasive authority, Plaintiffs conveniently ignore the actual standard identified in *Korsak*: Expert witnesses may rely on hearsay only when the information at issue is the type of information “reasonably relied upon by professionals in the field.” *Id.* at 1524; *see also* Fed. R. Evid. 703.

Plaintiffs must show that the April 30, 2008 e-mail is the type of information reasonably relied upon by pharmaceutical industry professionals to conclude defective product made it to market. (Doc. 551 at 1-4). But Plaintiffs' Opposition is silent on this issue. (*Id.*) If Plaintiffs had made an argument, it would have come up well short. They cannot credibly claim the April 30, 2008 e-mail is the type of information reasonably relied upon by professionals in the field when forming an opinion that defective product reached the market. Indeed, Plaintiffs' experts concede this e-mail is not reliable in that respect. (Doc. 527 at 2-3).

Even Dr. Bliesner acknowledged that the 2008 e-mail is not reliable enough to allow him to come to a “firm conclusion” that adulterated or defective Digitek® made it to market.

(Bliesner Dep. at 437:19-438:2, attached as Exhibit 14 to Doc. 522). In fact, Dr. Bliesner concedes that the e-mail is merely “something that starts a formal investigation. It’s a piece of data.” (*Id.* at 65:1-2). In other words, the information in the April 30, 2008 e-mail is a piece of data which, at best, would trigger an investigation by Dr. Bliesner into whether double-thick tablets reached the market. The 2008 e-mail is the beginning of the analysis, not the conclusion. (*Id.*) In addition, if Dr. Bliesner was conducting the investigation that would flow from review of the e-mail, he would measure the tablet to conclude whether it was double-thick or out of specification for thickness. (*Id.* 65:21-25). Plaintiffs’ expert Russell Somma, Ph.D., echoes the inability of the e-mail to support a conclusion, acknowledging it would be “impossible to accurately measure” a tablet enclosed within a blister pack. (Somma Dep. at 51:4-7, attached as Exhibit 15 to Doc. 522).

Despite Plaintiffs’ contrary assertions, the April 30, 2008 e-mail is inherently unreliable on its face for multiple reasons. (*See* Doc. 527 at 1-3). Perhaps most importantly, the author of the e-mail nowhere identifies the product as Digitek® manufactured by Actavis, as opposed to one of the other generic digoxin tablets that were on the market in April of 2008. (*See* Doc. 527-1). Plaintiffs ignore this issue. And Plaintiffs have set forth no evidence contradicting the substantial testimony and evidence that a double-thick tablet would not fit into a blister pack created and marketed by UDL and would shut down and damage UDL’s equipment. (*Id.* at 2-3).

There is nothing to indicate the report of a double-thick tablet is reliable or that this type of information is the type of information reasonably relied upon by experts like Dr. Bliesner to conclude defective product reached the market. Defendants have not been able to cross examine the individual who prepared the e-mail, or the employee who made the observation, about any of

the circumstances surrounding the observation of the tablet at issue. Defendants' Motion should be granted.

### **III. THE AFFIDAVIT OF LYNNE FARRELL MUST BE DISREGARDED.**

Plaintiffs attempt to bolster their reliance and Dr. Bliesner's reliance on the April 30, 2008 e-mail by submitting an affidavit executed by Lynne Farrell, who is apparently the individual who made the observation in the e-mail. (Doc. 562-1). This affidavit must be quickly disregarded and should be stricken for a host of reasons. (*See* Motion to Strike Affidavit of Lynne Farrell, being filed hereafter).

The affidavit was not timely filed—it was submitted long after fact discovery closed on April 1, 2011 in the MDL and May 2, 2011 in *McCornack*, and was even submitted five days after the deadline for filing opposition to Defendants' dispositive motions. (*Id.*) Plaintiffs attempt to try cure this glaring deficiency simply by calling the affidavit “supplemental evidence” and assert they “were unable to submit [the affidavit] any earlier” but offer no actual explanation for this contention. (Doc. 562 at 2). There is no indication the information in the affidavit was newly discovered after the operative deadline—it was more than 3 years old at that time and was timely produced by Mylan in discovery. (Doc. 562 at 1-2). Indeed, Plaintiffs' experts all read and referred to the e-mail in their expert reports which were produced over a year ago. There is nothing which indicates the affidavit could not have been timely submitted by Plaintiffs' August 24, 2011 briefing deadline. This belated effort should be excluded for the same Fed. R. Civ. P. 26 reasons articulated by defendants regarding Dr. Bliesner's new affidavit and Dr. Delgado's new affidavit.

Moreover, the affidavit is also inadmissible hearsay—it is an out of court statement offered for the truth of the assertion that double-thick Digitek® tablets were released to market.

(Doc. 562-1 at ¶8). No hearsay exception applies to the affidavit, and Defendants have no opportunity to examine Ms. Farrell about any of her affidavit testimony.

The affidavit also suffers from the same deficiencies and is every bit as unreliable as the April 30, 2008 e-mail. Most notably, again, there is no testimony that the tablet being discussed actually was Digitek® produced and released to market by Actavis. (Doc. 562-1 at 2). And while the witness may be an experienced nurse and observer of blister packs generally, the accurate measurement of a tablet within a blister pack is another matter entirely.

#### **IV. CONCLUSION**

The April 30, 2008 e-mail allegedly indicating a double-thick Digitek® tablet was observed in the market is hearsay and does not fit any hearsay exception. Nor is it the type of information upon which pharmaceutical professionals typically reasonably rely to conclude that defective product reached the market. This Court should preclude reference to this e-mail and bar any Plaintiffs' expert who seeks to offer a defect or causation opinion on the basis of this e-mail. Ms. Farrell's affidavit does not fix the problems with the April 30, 2008 e-mail and should also be excluded.

Respectfully submitted,

GUTHRIE & THOMAS, PLLC

Rebecca A. Betts, LIAISON COUNSEL  
500 Lee Street East, Suite 800  
Charleston, West Virginia 25301  
Tel: (304) 345-7250  
Fax: (304) 345-9941  
E-mail: [rabetts@agmtlaw.com](mailto:rabetts@agmtlaw.com)

*Attorney for Defendants*

TUCKER ELLIS & WEST LLP

By: /s/ Richard A. Dean  
Richard A. Dean (Ohio Bar #0013165),  
CO-LEAD COUNSEL  
Matthew P. Moriarty (WV Bar # 4571;  
Ohio Bar 0028389), CO-LEAD COUNSEL  
925 Euclid Avenue, Suite 1150  
Cleveland, Ohio 44115-1414  
Tel: (216) 592-5000  
Fax: (216) 592-5009  
E-mail: [richard.dean@tuckerellis.com](mailto:richard.dean@tuckerellis.com)  
[matthew.moriarty@tuckerellis.com](mailto:matthew.moriarty@tuckerellis.com)

*Attorneys for Defendants Actavis Totowa LLC,  
Actavis Inc., and Actavis Elizabeth LLC*

SHOOK, HARDY & BACON LLP

Harvey L. Kaplan, CO-LEAD COUNSEL  
Madeleine M. McDonough, CO-LEAD  
COUNSEL  
2555 Grand Blvd.  
Kansas City, Missouri 64108-2613  
Tel: (816) 559-2214  
Fax: (816) 421-5547  
E-mail: [hkaplan@shb.com](mailto:hkaplan@shb.com)  
E-mail: [mmcdonough@shb.com](mailto:mmcdonough@shb.com)

*Attorneys for Mylan Pharmaceuticals Inc.,  
Mylan Bertek Pharmaceuticals Inc., and  
UDL Laboratories, Inc.*

**CERTIFICATE OF SERVICE**

I hereby certify that on Septemeber 7, 2011, a copy of the foregoing **REPLY IN SUPPORT OF DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE UNRELIABLE HEARSAY** was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

GUTHRIE & THOMAS, PLLC

Rebecca A. Betts, LIAISON COUNSEL  
500 Lee Street East, Suite 800  
Charleston, West Virginia 25301  
Tel: (304) 345-7250  
Fax: (304) 345-9941  
E-mail: [rabetts@agmtlaw.com](mailto:rabetts@agmtlaw.com)

*Attorney for Defendants*

SHOOK, HARDY & BACON LLP

Harvey L. Kaplan, CO-LEAD COUNSEL  
Madeleine M. McDonough, CO-LEAD COUNSEL  
2555 Grand Blvd.  
Kansas City, Missouri 64108-2613  
Tel: (816) 559-2214  
Fax: (816) 421-5547  
E-mail: [hkaplan@shb.com](mailto:hkaplan@shb.com)  
E-mail: [mmcdonough@shb.com](mailto:mmcdonough@shb.com)

*Attorneys for Mylan Pharmaceuticals Inc.,  
Mylan Bertek Pharmaceuticals Inc., and UDL  
Laboratories, Inc.*

TUCKER ELLIS & WEST LLP

By: /s/ Richard A. Dean  
Richard A. Dean (Ohio Bar #0013165),  
CO-LEAD COUNSEL  
Matthew P. Moriarty (WV Bar # 4571;  
Ohio Bar 0028389), CO-LEAD COUNSEL  
925 Euclid Avenue, Suite 1150  
Cleveland, Ohio 44115-1414  
Tel: (216) 592-5000  
Fax: (216) 592-5009  
E-mail: [richard.dean@tuckerellis.com](mailto:richard.dean@tuckerellis.com)  
[matthew.moriarty@tuckerellis.com](mailto:matthew.moriarty@tuckerellis.com)

*Attorneys for Defendants Actavis Totowa LLC,  
Actavis Inc., and Actavis Elizabeth LLC*